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LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Stretchable conducting lead

The invention is described in the following statement:

Technical Field

The present invention relates to an electrically conducting lead suitable for use with an implantable medical device. More particularly, the present invention relates to an implantable conducting lead having a layered conducting element with multiple conducting portions.

Background of the Invention

Medical devices capable of being implanted in the body to provide therapy to a recipient have become increasingly common over recent times. Devices such as pacemakers, defibrillators, cochlear implants and functional electrical stimulation systems have all proven successful in providing useful therapy to recipients across a broad spectrum of applications.

Fundamental to all such devices is the provision of an implantable stimulator unit fixedly implanted within the body of the recipient. This stimulator unit is typically capable of receiving control signals from a device external to the recipient via a transcutaneous link. As well as control signals, the implanted stimulator unit may also receive power from an external device via the same or an alternative transcutaneous link.

Upon receival of control signals and/or power, the stimulator unit typically then directs and controls the stimulation to be applied by the system. In the case of cochlear implants, the stimulator system may select the desired electrode and send a stimulation pulse to the electrode having a desired amplitude and pulse width. Typically, the stimulator unit is provided with dedicated electronics which enable it to decode the received control signals and control the flow of stimulation current from the stimulator unit to the desired stimulation site.

With advancement in battery technology, it is becoming increasingly popular for implanted stimulator units to be provided with their own power source, usually in the form of a rechargeable battery, to provide operating power to the electronics of the stimulator unit. In this regard, such devices can operate, at least for a period of time without the need for any external devices.

For pacemaker devices this is important as they do not need to rely upon a constant link with an external device to remain operational, and can continue to perform their important function with the reliance of their own power source. For devices such as cochlear implants, there is an increasing desire for such devices to operate invisibly without the need for external devices and for this reason the use of an implantable stimulator unit with its own power source is becoming increasingly desirable.

Apart from the implanted stimulator unit which houses the electronic circuitry and power source necessary to control the therapy applied by the implantable device, a means for actually applying the therapy is also fundamental to such systems. In most cases, the means for applying the therapy is typically an electrode or electrodes, strategically positioned close to the desired stimulation site, for applying the electrical stimulation to that particular site.

The stimulating electrodes are typically positioned remote from the implanted stimulator unit. For example, in cochlear implant applications the stimulator unit is typically positioned in a recess in the skull whilst the electrodes are implanted in the cochlea close to the desired nerves. In this regard, a lead connecting the electrodes and the stimulator unit is required, and such leads need to be designed in a manner to ensure that the electrical stimulation is delivered safely to the appropriate electrodes and that the link between the stimulating electrodes and the stimulator unit is sturdy and reliable.

Traditionally, the common way of providing this electrical connection between the stimulator unit and the electrodes has been via conducting wires. Such wires typically communicate with the electronics within the stimulator unit via a hermetic feedthrough device and are welded to the terminating electrodes thereby forming a conductive path from the stimulator unit to the electrodes along which the stimulation current can flow. Typically, the lead is insulated from the surrounding tissue via a coating of insulative material, such as silicone.

In providing such an implantable connecting lead, it is important that the lead is capable of a degree of flexibility to compensate for any movement between the implantable stimulator and the electrodes, such as movement which may naturally occur due to body growth. Without such flexibility, excessive force can be experienced in the lead, particularly at the connection points such as at the feedthrough, resulting in the lead failing to act as a conductor. Further to this, providing a flexible rather than a rigid connection between the electrodes and the stimulator unit provides for easier surgical placement of the electrodes close to the desired stimulation site, which ensures that the surgical procedure is simpler and requires less surgical skill.

The typical method of providing a lead capable of a degree of flexibility is to wrap the wires, either individually or as a group, in a helical arrangement along the length of the lead. The wires can then be enclosed in a coating of body compatible polyurethane or a suitable nonconductive plastic, which has a degree of flexibility. In this way, the lead can experience a degree of elongation without placing undue stress on the wires or at the point where the wires connect to the stimulator unit. Examples of such leads are described in US Patent No 4,835,853 and International Patent Application No WO 83/04182.

One problem with such prior art methods is that it is difficult to sort the wires in a manner that makes it easily identifiable which electrode they are connected to. As such, following the formation of the lead, it is a time consuming process to individually test each wire and identify which electrode it is connected to and to then ensure that this wire is connected to the stimulator unit in the appropriate manner. This problem is further exacerbated when the number of stimulating electrodes increases and hence the number of wires increases, such as in cochlear implants where the number of electrodes can be greater than 22.

The present applicant has developed a new process for manufacturing electrodes and conductors connecting said electrodes to a stimulator/control unit. This process and the resulting products are described in detail in International Patent Application No. PCT/AU02/00575, the contents of which are incorporated herein by reference. In essence, this process results in the formation of an electrode array comprising of a stack of offset electrodes,

layered on top of each other. Each of the electrodes has a respective conducting portion extending from the electrode, with the conducting portion and the electrode being integral and constructed from one piece of material. In this regard, a connecting lead is provided consisting of a plurality of layered, parallel conducting portions extending in a longitudinal direction. Such a lead therefore resembles a layered ribbon conductor, considerably different from conventional wire leads.

With such a change in the traditional structure of conventional wire conductors used in implantable devices, there is a need to provide a conducting lead that is capable of maintaining said conductors in a flexible and insulative environment. Further to this, there is a need to provide a conducting lead that can take advantage of the ordered structure of layered conducting wires so that the conductors can be easily sorted and connected to the appropriate stimulator.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an electrically conducting lead comprising:

a body of relatively electrically insulative material; and

a relatively electrically conductive element extending through at least a portion of said insulative body in a helically wound arrangement;

wherein said electrically conductive element comprises a plurality of layers of electrical conductors.

In a preferred embodiment of this aspect, each layer of electrical conductors is made up of a plurality of separate electrical conductors, with the position of each electrical conductor being constant with regard to its neighbour and the position of each layer of electrical conductors being constant with regard to its neighbouring layer over the length of the conducting lead.

In a further embodiment of this aspect, the electrically conductive element extends from a first end to a second end of the lead.

According to a second aspect, the present invention is an electrically conducting lead comprising:

a body of relatively electrically insulative material; and

a relatively electrically conductive element extending through at least a portion of said insulative body in a wound arrangement;

wherein said electrically conductive element comprises a plurality of layers of electrical conductors and the longitudinal extent of each of said electrical conductor over said portion of the lead is substantially identical.

In this aspect, the wound arrangement of the electrically conductive element is preferably a helically wound arrangement. In this regard, the spacing or pitch of the wound arrangement can vary or be identical along said arrangement.

In a further embodiment of this aspect, the electrically conductive element extends from a first end to a second end of the lead. In this embodiment, the longitudinal extent of each of said electrical conductors over the length of the lead from the first end to the second end is substantially identical. More preferably, the longitudinal extent of the electrical conductors is identical.

In one embodiment, the electrically conductive element extending through said portion of the insulative body is wound in an anticlockwise direction and then in a clockwise direction if looking at the lead from the first

end of the lead. It will be understood that if one was to look at the lead from the second end, the anticlockwise turns would appear to be turning clockwise and the clockwise turns anticlockwise.

In a preferred embodiment, the length of the conductive element that is wound in a anticlockwise manner is substantially equal, and preferably equal, to the length of the conductive element that is wound in a clockwise manner.

At the transition from anticlockwise to clockwise turns, the conductive element is preferably folded back on itself.

In another embodiment, the conductive element continues to be wound in an anticlockwise manner or clockwise manner, when viewed from the first end, for the length of said portion of the insulative body. In this embodiment, the layer is preferably twisted by 180° at a location along the length of the body. In a preferred embodiment, the twist is about, and preferably exactly at, the midway point of the length of the wound conductive element in the lead.

Each layer of the conductive element is preferably comprised of a plurality of separate electrical conductors. Each layer can have the same number of conductors as the other layers in the element. In another embodiment, the number of conductors of at least one of the layers can vary from the number in other layers of the element.

According to a third aspect, the present invention is an electrically conducting lead comprising:

a body of relatively electrically insulative material; and

a relatively electrically conductive element extending through at least a portion of said insulative body in a wound arrangement;

wherein said electrically conductive element comprises a plurality of layers of electrical conductors with the number of conductors of at least one of the layers varying from the number of conductors in other layers of the element.

In a further embodiment of this aspect, the electrically conductive element extends from a first end to a second end of the lead. In this embodiment, the longitudinal extent of each of said electrical conductors over

the length of the lead from the first end to the second end is substantially identical. More preferably, the longitudinal extent of the electrical conductors is identical.

In this aspect, the wound arrangement of the electrically conductive element is preferably a helically wound arrangement. In this regard, the spacing or pitch of the wound arrangement can vary or be identical along said arrangement.

In each of the aspects, the electrical conductors are preferably made of a platinum material. More preferably, the electrical conductors are made from a sheet of platinum material. Each of the leads preferably has a first end that is attachable to or is integrally attached to an electrode pad. Each of the leads further preferably has a second end that is connectable to a stimulator unit.

In one embodiment of each of the aspects, the lead is preferably body implantable. In this regard, the materials used to form the lead are preferably suitable for implantation in the body of a recipient.

The electrically insulative body is further preferably formed from a flexible material, such as silicone rubber or parylene.

According to a fourth aspect, the present invention is a method of manufacturing a lead according to one of the preceding aspects, the method comprising the steps of winding a conductive element as defined herein relative to and around an insulative body as defined herein.

In one embodiment, the conductive element can be loaded in a spindle, with one end of the element attached to one end of the insulative body. The insulative body can then be turned in one direction, eg a clockwise direction, causing the conductive element to exit the spindle and become wound around the insulative body. The spindle can be moved longitudinally relative the length of the insulative body.

In one embodiment, the spindle could move in a clockwise direction relatively around the insulative body. If desired, at a mid point along the length

of the insulative body, the direction of rotation of the insulative body with respect to the spindle can change to an anticlockwise direction. At this point, the conductive element is caused to fold upon itself such that what was an inner layer of the conductive element becomes the outer layer and vice versa. The conductive element is then wound onto the insulative body in an opposite direction for a length equal to that previously wound onto the insulative body. This results in all layers of the conductive element travelling the same distance and therefore being aligned at both ends of the lead.

Following winding of the conductive element, the insulative body can be coated in another layer of insulative material, such as silicone.

In an alternative method, respective ends of the conductive element can be fixed to respective ends of the insulative body, with the spindle positioned midway between both ends of the insulative body. Once again, the insulative body can be rotated relative to the spindle or the spindle can rotate relative to the insulative body to cause the conductive element to be wound onto the insulative body. As the conductive element is wound onto the insulative body, the spindle moves relatively closer to the insulative body to ensure that the pitch of winding is controlled as desired.

At the mid-point, the winding is complete and the conductive element is removed from the spindle, with all layers of the conducting element travelling the same distance over the length of the insulative body.

In a still further embodiment, the conductive element is again mounted in a spindle with one end of the conductive element connected to one end of the insulative body. When the spindle has wound the conductive element to the mid-point, the spindle is preferably relatively rotated about or exactly 180°. This causes the conductive element to twist such that what was previously the inner layer of the conductive element becomes the outer layer and what was previously the outer layer becomes the inner layer of the conductive element.

Following the formation of the twist in the conductive element, the insulative body is preferably continued to relatively rotate in the same direction to complete the winding.

Use of the methods as defined herein result in the formation of a lead comprising an insulative body having a conductive element wound thereon, with preferably, the conductors of the element extending the same length through the lead.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 is a view of a prior art lead used in implantable devices;

Fig. 2 is a view of electrode pads and conducting portions according to one embodiment of the present invention;

Fig. 3 is a top view of an electrode array arrangement;

Fig. 4 is a cross sectional view of the conductive element of Fig. 3 along X-X;

Fig. 5 is a side view of the conductive element of Fig. 4;

Fig. 6 is a view of one embodiment of the conductive lead according to the present invention;

Fig. 7a and 7b are end views of the conductive element of Fig. 6;

Fig. 8 is a side view of one end of the conductive element of Fig. 7; and

Fig. 9 is a view of another embodiment of the conductive lead of the present invention;

Fig.10 is a view of yet another embodiment of the conductive lead of the present invention;

Figs. 11a-11c are views of the steps associated with one embodiment of constructing the conductive lead as shown in Fig. 9;

Figs. 12a-12c are views of the steps associated with another embodiment of constructing the conductive lead as shown in Fig. 9; and

Figs. 13a-13c are views of the steps associated with one embodiment of constructing the conductive lead as shown in Fig. 10.

Best Mode for Carrying Out the Invention

Figure 1 represents a conventional conducting lead 10 used in implantable medical devices. This lead 10 has a plurality of conducting wires 2 extending therethrough. Each of these wires 2 can be connected at one end to a stimulator unit and at the other end to a stimulating/sensing electrode so that an electric signal can be transmitted from the stimulator unit to the corresponding electrode. The wires 2 are typically embedded in a body compatible material 4 such as polyurethane or an organo-silicon polymer or any other suitable non-conductive plastic.

Typically, the body compatible material 4 can undergo some degree of extension/flexibility. As shown, each of the wires 2 are arranged within the body compatible material 4 in a helical manner to ensure that the lead 10 can extend without placing undue stress on the wires 2. As is shown, the pitch of the wire helix can also be altered to vary the flexibility of the conducting lead 10.

Figures 2 and 3 depict one arrangement of stimulating electrode pads and leads for use in the present invention. This particular arrangement is described in more detail in International Patent Application No. PCT/AU02/00575, which is incorporated herein by reference. In this application the present invention is described in relation to a cochlear implant application, however it is envisaged that the present invention is also applicable to other applications where a conducting lead is employed.

Figure 2 shows the electrode pads 12 and conducting portions 14 being formed in a series of groups A-F. As is clearly evident, the electrode pads 12 and the conducting portions 14 are formed as one piece, from a sheet of conductive material such as platinum, in accordance with the methods described in PCT/AU02/00575. The electrode pads 12 and conducting portions 14 are made from a sheet of platinum or similar conducting material, and covered in a coating of electrically insulating material such as silicone rubber or a polymer material such as parylene.

The electrode pads 12 are then shaped accordingly, in this instance into a U-shape, with the conducting portions 14 running centrally from the electrode pads 12. In this example, each of the electrode array groups A-F are formed separately, but preferably from a single sheet of platinum, thereby forming a series of electrode arrays, with each array consisting of a plurality of electrode pads 12 with centrally positioned conducting portions 14 connected thereto.

Each of the electrode array groups A-F can be arranged longitudinally, to form a multi-electrode array structure 15, in this instance a cochlear implant electrode array. In the embodiment shown, electrode array group A is stacked and positioned on top of electrode array group B which is then stacked and positioned on top of electrode array group C, and so on. This arrangement produces an electrode array structure that is shown more clearly from the top view of the structure provided as Figure 3.

In the embodiment shown in Fig. 3, the electrode array structure 15 consists of 30 individual electrode pads 12, with each electrode pad 12 having an integral conducting portion 14 extending therefrom and running centrally along the electrode array structure 15. Following the formation of the electrode array structure 15, the array can be moulded in a suitable bio-combatable material such as silicone and shaped accordingly, as is known in the art and which is not essential to an understanding of the present invention.

In the embodiment described, the electrode array structure is shown consisting of 30 individual electrode pads 12, however it should be appreciated that the electrode array structure could consist of any number of electrode pads and still be applicable to the present invention.

In an electrode array constructed in the manner shown in Figures 2 and 3, the conducting portions 14 resulting from such an arrangement will be formed in the manner shown in Figure 4. In this regard, Figure 4 can be considered as an end view or cross-section of the conducting portions 14 of Figure 3 along line X-X. As is clearly evident, the conducting portions 14 associated with each of the electrode array groups A-F are arranged in a layered format, with the most distant electrode array group A being the top layer, and the most proximal electrode array group F being the bottom layer, this layered format being generally referred to as the conducting element 18.

This conducting element 18 is more clearly shown in Figure 5, which is a side view of the conducting element 18 shown in Figure 4. From these figures it is evident that the resulting format of the conducting element 18 has a layered, ribbon-like format with each of the conducting portions 14 connected to an integral electrode pad 12 at one end and connectable to a stimulator unit at the other end via a suitable feedthrough device (not shown). It is also to be understood in looking at Figure 4 that each of the conducting portions 14 are electrically insulated from all of the other conducting portions in the element 18.

In the embodiment shown in Figure 4, the conducting element 18 is made up of six layers (A-F) however the number of layers is dependant upon the design of the electrodes and as such any number of layers could be used as desired. Also, Figure 4 shows the conducting element 18 being made up of layers having different numbers of conducting portions 14, for example layer A is shown having 3 conducting portions, layer B with 4, layer C with 5 and layers D-F with 6 conducting portions. It should be appreciated that the number of conducting portions 14 provided in each of the layers is not critical to the present invention as the layers could all contain the same number of conducting portions or all contain different numbers and still fall within the scope of the present invention.

In the embodiment shown in Figure 4, each of the conducting portions 14 are shown having a substantially square cross-sectional area. It should be appreciated however that the conducting portions could be of any cross sectional shape. The dimensions of the conducting portions 14 shown also

vary dependant upon the desired application. Possible dimensions of the conducting portions may have a width Y of between about 5-50 μm and a thickness Z of between about 10-100 μm. In the embodiment shown the width Y of the conducing portions is 25μm and the thickness Z is 15 μm.

As the conducting portions 14 together form a layered, ribbon-like conducting element 18, each of the portions 14 cannot easily be separated and individually coiled to form a helical conducting lead as is typical in the prior art and shown in Figure 1. Instead, it is desirable to form a connecting lead wherein the conducting element 18 is maintained in a layered, ribbon format within a coating of insulative and biocompatible material such as silicone or parylene.

Therefore the formation of such a lead that is capable of providing adequate flexibility and elongation as well as being bio-compatible and insulative is important in providing a safe and effective connection between an implantable stimulator unit and stimulating electrodes.

Figure 6 shows one embodiment of a conducting lead according to the present invention. In this embodiment, the lead 20 includes a conducting element 18 helically wound within a body of insulative material having good body compatibility, such as silicone or parylene. As is shown, the conducting element 18, which is shown in cross-section detail in Figures 7a and 7b, is made up of a plurality of layers with each layer consisting of a plurality of conducting portions 14. The pitch of the helix can be controlled so that the flexibility of the lead 20 can be altered as desired. One end of the lead 20 is preferably connected to a stimulator unit, whilst the other end of the lead may be connected to stimulating electrodes, such as those shown in Figures 2 and 3.

Figures 7a and 7b show cross-sectional views of the conducting element 18 at each end of the lead 20. As shown in Figure 7a, the conducting element 18 may consist of a plurality of layers of conducting portions 14 with each layer having the same number of conducting portions 14, or as is shown in Figure 4, each layer could have different numbers of conducting portions.

In this embodiment, by providing a layered conducting element 18 the position of the conducting portions 14 with respect to each other can be maintained throughout the length of the lead 20. As is shown in Figures 7a and 7b, conducting portion A1 can be easily identifiable at both ends of the lead 20 allowing for easy determination and connection of the electrode to the appropriate contact. In prior art devices whereby individual or bunched wires are helically wound within an insulative material (as depicted in Fig. 1), such direct identification is not easily provided for. Providing such easy identification of the conducting portions 14 allows for considerable time reductions in the manufacture of such devices. Without this, the task of connecting the lead to the stimulator is particularly arduous, as each connecting portion must be individually tested to determine which electrode pad 12 it is connected to. This time saving aspect becomes particularly important when the number of electrode pads 12 is increased, requiring much sorting of the conducting portions 14 prior to connection to the stimulator unit.

In the embodiment shown in Figure 6, each of the layers of the conducting element 18 are not aligned at both ends. The result of this is depicted in Figure 8, which shows one end of the conducting element 18 of the present invention. This difference in alignment is because the outer layer (A) of the conducting element 18 will travel a greater distance in the helix than the inner layer (F) of the conducting element 18. In some instances, the alignment of each of the conducting portions 14 at both ends will not be critical, as the conducting portions may be separately connected to the stimulator unit via an appropriate feedthrough device.

Figures 9 and 10 show embodiments of the present invention similar to the embodiment shown in Figure 6, but which provide for alignment of the conducting portions 14 at both ends of the lead 20.

In the embodiment shown in Fig 9, the conducting element 18 is helically wound in one direction, eg anti-clockwise, for a portion of the length of the lead 20, and then helically wound in an opposite direction, eg clockwise, for another portion of the length of the lead 20. In this regard, it is preferred that the conducting element 18 is wound such that each layer travels the same distance over the length of the lead, providing alignment of the conducting portions at

both ends. This can be achieved by winding the conducting element 18 in one direction for half the length of the lead 20 and at a midpoint 22, winding the conducting element 18 in the opposite direction for the remaining half of the lead. Alternatively, the conducting element 18 may be wound in alternative directions for a number of cycles over the length of the lead, ensuring that the cycles of both the clockwise and anticlockwise windings are identical over the length of the lead 20.

By controlling the point 22 at which the winding of the conducting element 18 changes from clockwise to anti-clockwise, each layer of conducting portions 14 of the conducting element 18 can be wound so that they each travel the same distance over the length of the lead 20. In the embodiment shown in Figure 9, the point 22 where the winding changes direction, is achieved by folding the conducting element back upon itself thereby causing the inside layer (shown as hatched) to become the outside layer and what was previously the outside layer (curved line) becomes the inside layer.

In the embodiment shown in Figure 10, an alternative method of achieving this alignment is shown wherein the conducting element is twisted by 180 degrees causing what was previously the inside layer to become the outside layer and what was previously the outside layer to become the inside layer. This way, the direction of winding does not have to be changed and by controlling the number of turns and the pitch of the winding the distance travelled by each layer of the conducting element 18 over the desired length of the lead 20 can be easily controlled.

A lead 20, such as that shown in Figure 9 can be manufactured in the manner shown in Figures 11a-11c. In Fig. 11a, a silicone tube 25 is shown placed over a mandrel 27 extending through the silicone tube 25 and supported at both ends by chucks (not shown). A spindle 26 is then loaded with the conducting element 18 for winding onto the silicone tube 25. As shown in Fig. 11a, the conducting element 18 is first fixed at one end of the silicone tube 25 prior to winding.

As shown in Fig 11b, the chucks supporting the mandrel 27 are then turned in one direction, eg a clockwise direction, causing the conducting

element 18 to exit the spindle 26 and become wound around the silicone tube 25. The spindle 26 can move longitudinally along the length of the silicone tube 25 as it rotates. It will be appreciated that the tube 25 could also be moved longitudinally relative to a stationary or moving spindle 26.

In one embodiment, the spindle 26 could move in a clockwise direction around the silicone tube 25. At a mid point, shown in Fig. 11b, the direction of rotation of the silicone tube with respect to the spindle 26 can change. At this point the conducting element 18 is then folded upon itself, as described in relation to Fig. 9, such that the inside layer becomes the outside layer and vice versa.

As shown in Figure 11c, the direction of rotation of the silicone tube 25 then changes from clockwise to anti-clockwise, and the conducting element 18 is then wound onto the silicone tube 25 in an opposite direction. This results in all layers of the conducting element travelling the same distance and therefore being aligned at both ends of the lead. Following winding of the conducting element 18, the silicone tube 25 and mandrel 27 can be removed from the chucks and coated in another layer of insulative material, such as silicone. The mandrel 27 can then be removed from the silicone tube 25 and further insulative material such as silicone can then be injected into the space left by the mandrel 27 to form a lead 20 as shown in Fig. 9.

An alternative method of manufacturing the lead shown in Fig. 9 is shown in Figs. 14a-14c. In this method the conducting element 18 is fixed at both ends to the silicone tube 25, and the spindle 26 is positioned midway between both ends of the silicone tube 25, as shown. Once again, the silicone tube 25 can be rotated relative to the spindle 26 or the spindle 26 can rotate relative to the silicone tube 25 to cause the conducting element 18 to be wound onto the silicone tube 25. As the conducting element 18 is wound onto the silicone tube 25, the spindle moves relatively closer to the silicone tube 25 to ensure that the pitch of winding is controlled as desired.

At the mid-point, as shown in Fig 12c, the winding is complete and the conducting element 18 is removed from the spindle, with all layers of the

conducting element travelling the same distance over the length of the silicone tube 25, producing a lead 20 as shown in Fig. 9.

A lead 20, such as that shown in Figure 10 can be manufactured in the manner shown in Figs 13a-13c. In Fig. 13a, the same arrangement as that described in relation to Figure 11a is used. However, in this embodiment, when the spindle 26 has wound the conducting element 18 to the mid-point, as shown in Fig 13b, the spindle 26 is rotated 180 degrees, as shown. In this regard, the conducting element 18 is "twisted" such that what was previously the inner layer of the conducting element 18 becomes the outer layer and what was previously the outer layer becomes the inner layer of the conducting element 18. This is shown in more detail in Fig. 10.

Following this "twist", the silicone tube 25 and mandrel 27 arrangement is rotated in the same direction and the winding is completed. In this regard, a lead similar to or the same as that shown in Fig. 10 is created with the winding occurring in one direction similar to that shown in Fig. 6.

Whilst the above three embodiment describe a silicone tube 25 forming the winding surface, it should be appreciated that other such materials are also envisaged to be used to create such a lead. Other such materials could be parylene or any other material that is both insulative and flexible and which is also body compatible.

The present invention therefore maintains the layered nature of the conducting element and provides a conducting lead that ensures easy identification of the conducting portions and their associated stimulating pads. The present invention also provides for a flexible and coiled lead that aligns each of the layers of the conductor at either end of the lead.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this seventeenth day of October 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

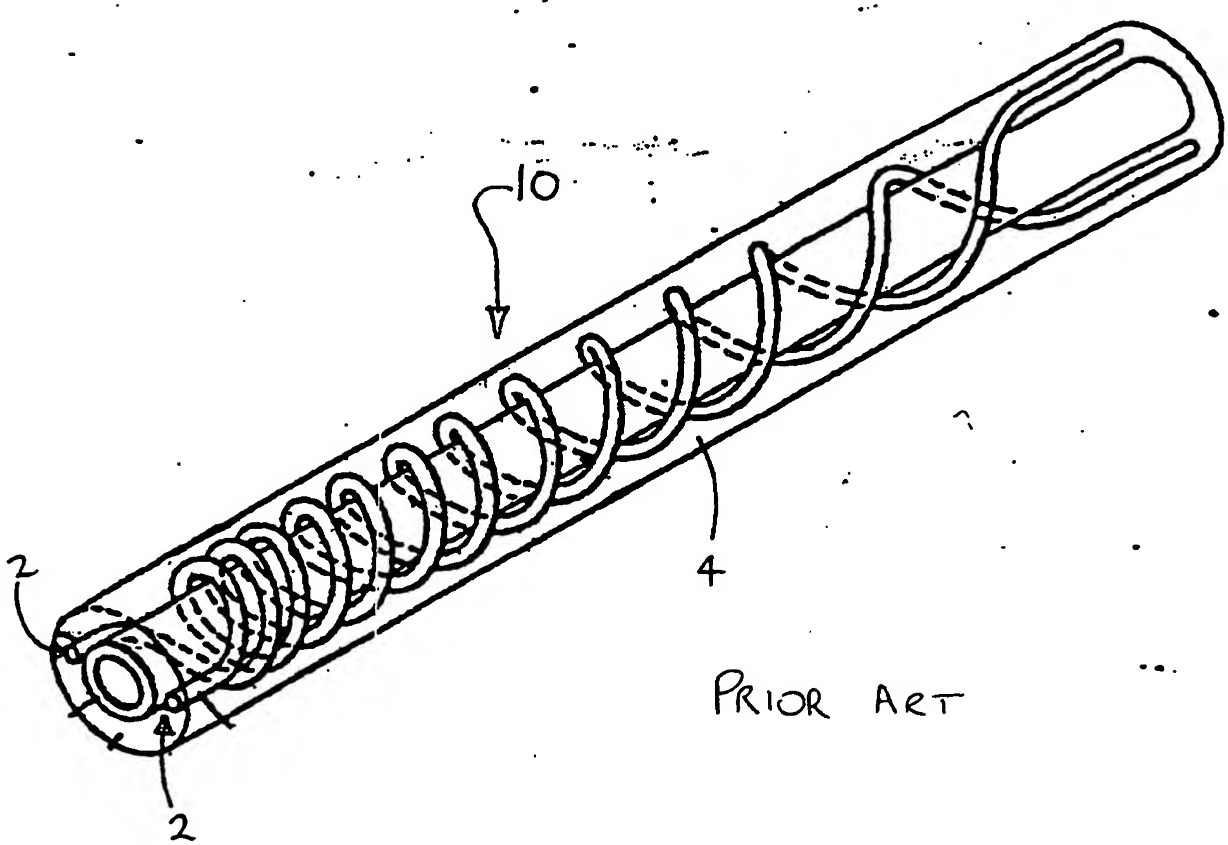

Figure 1.

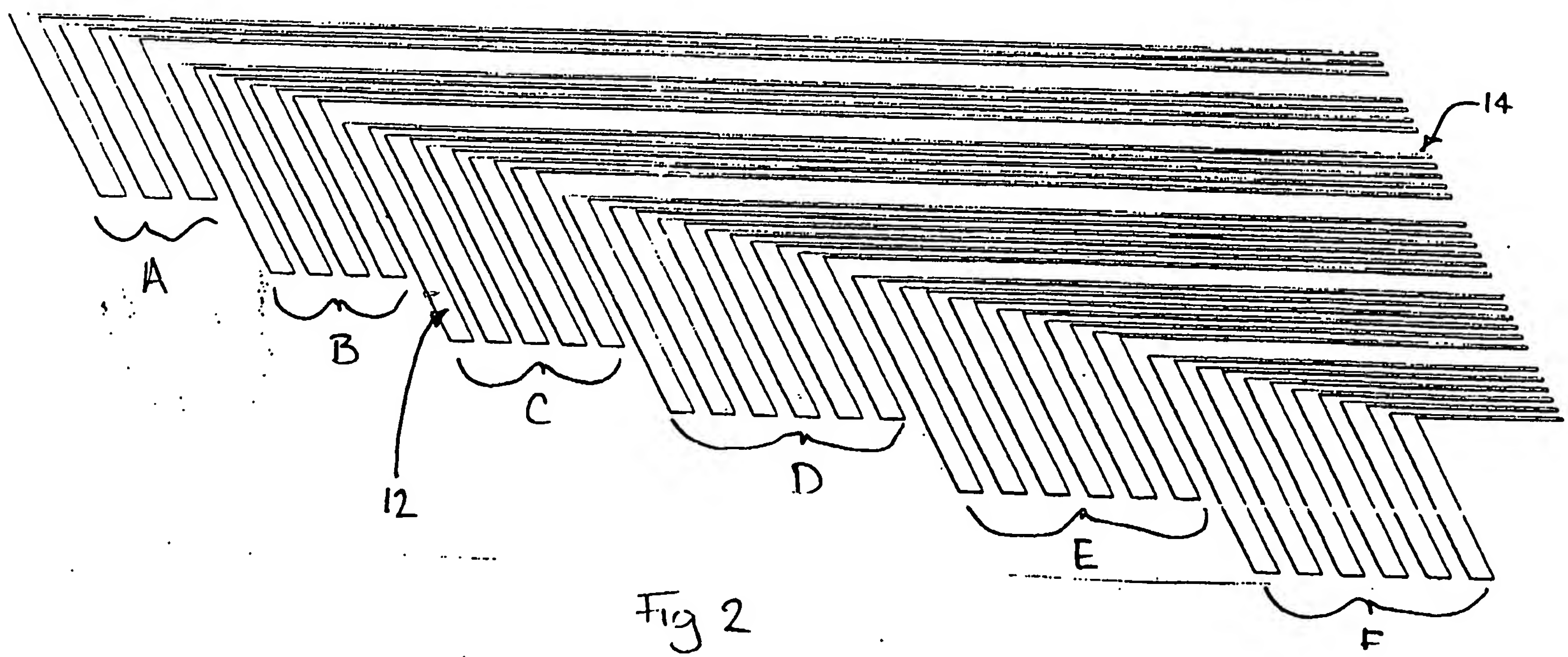

Fig 2

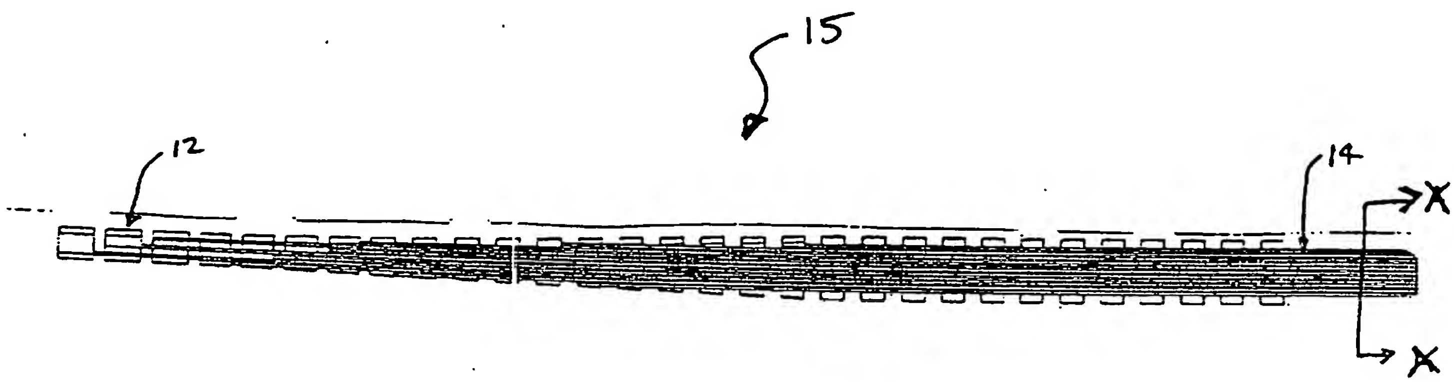

Fig. 3

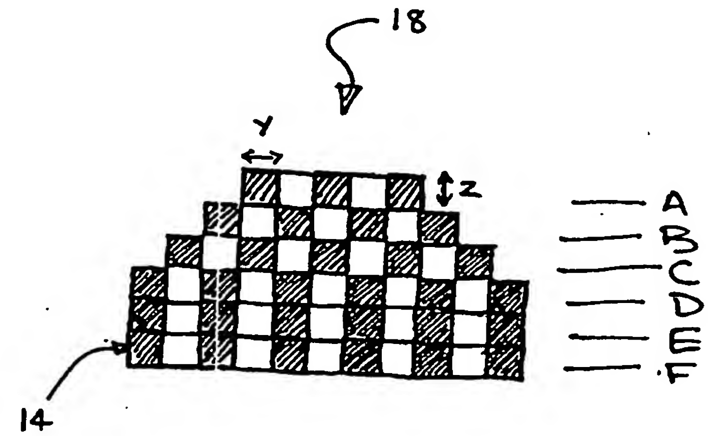

Fig 4

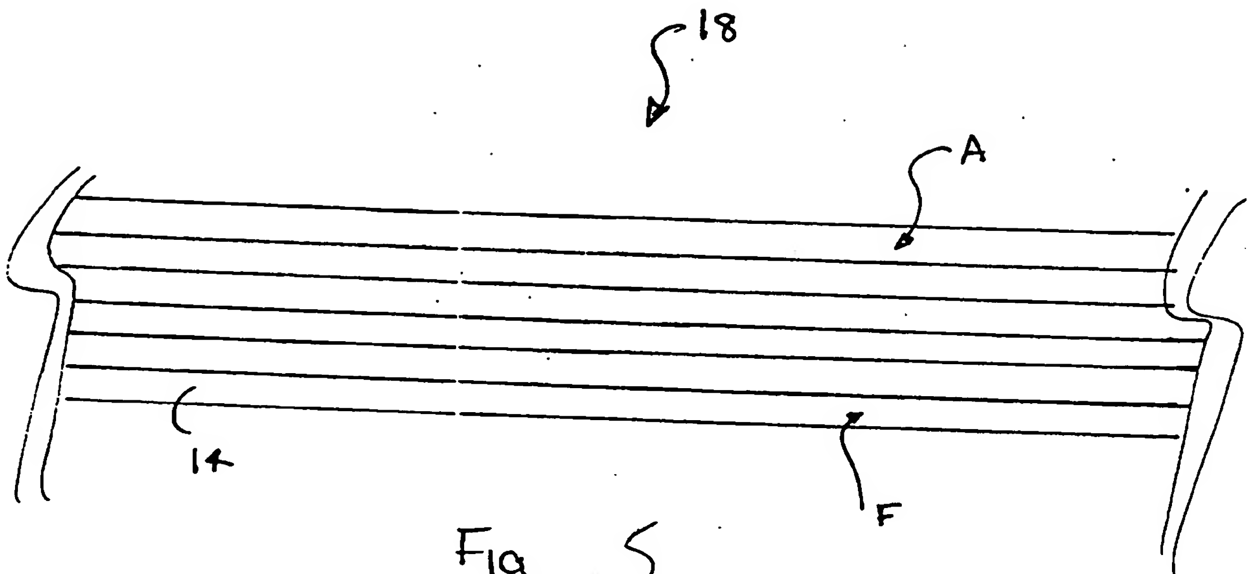

Fig 5

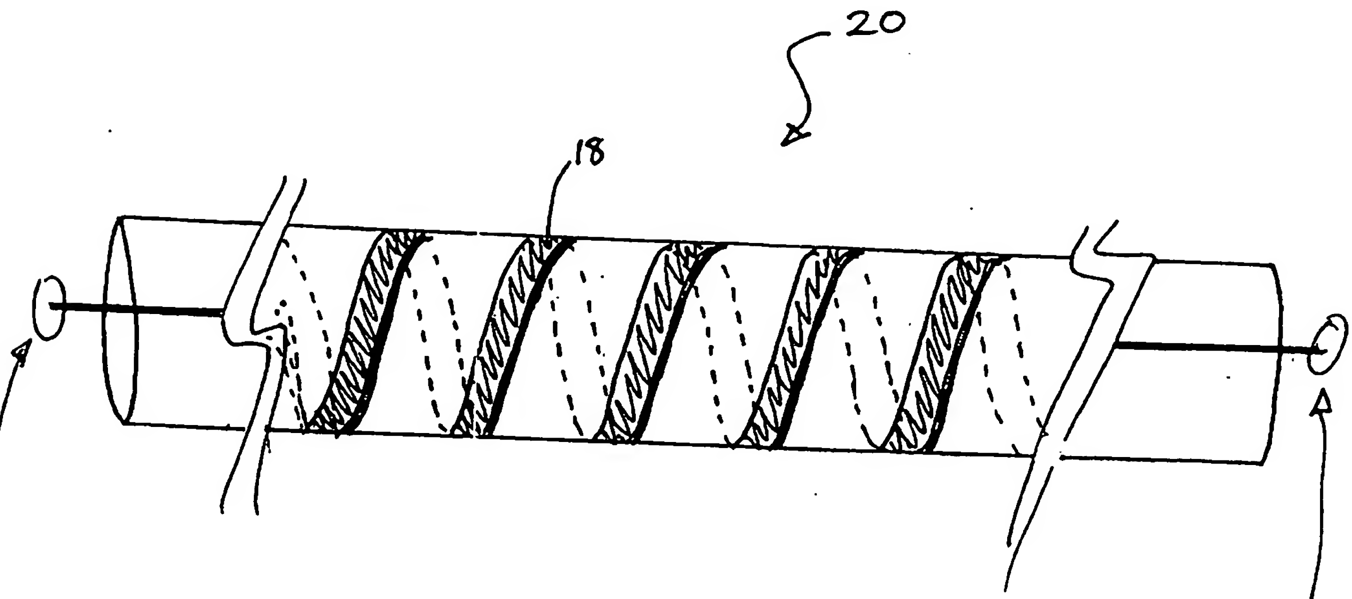

Fig. 6

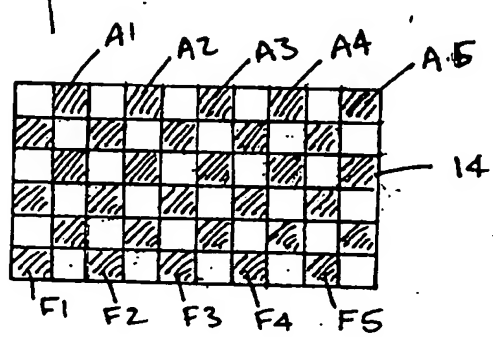

Fig. 7a

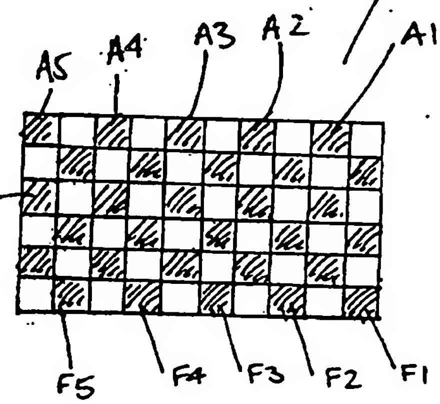

Fig. 7b

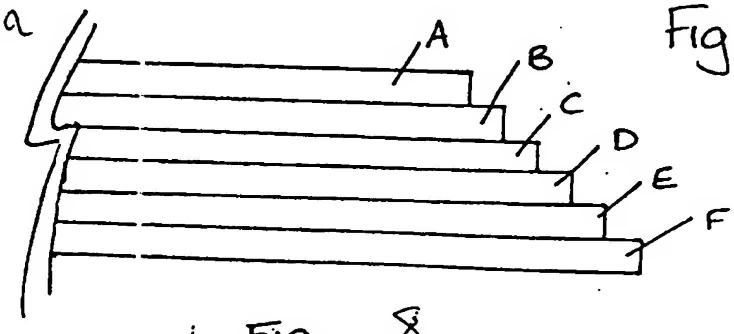

Fig. 8

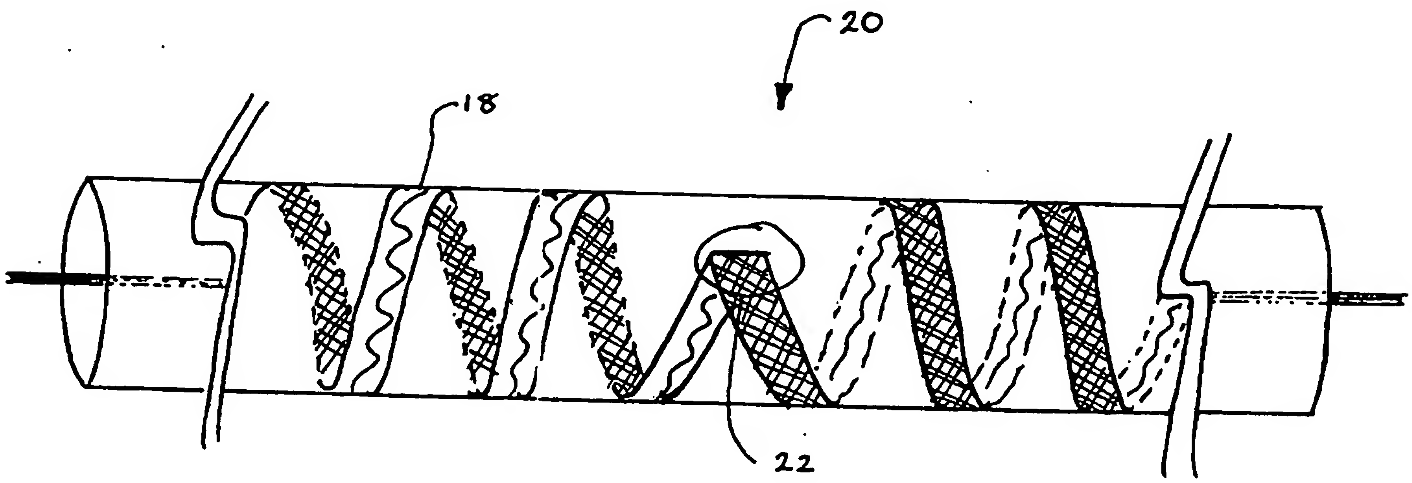

Fig. 9

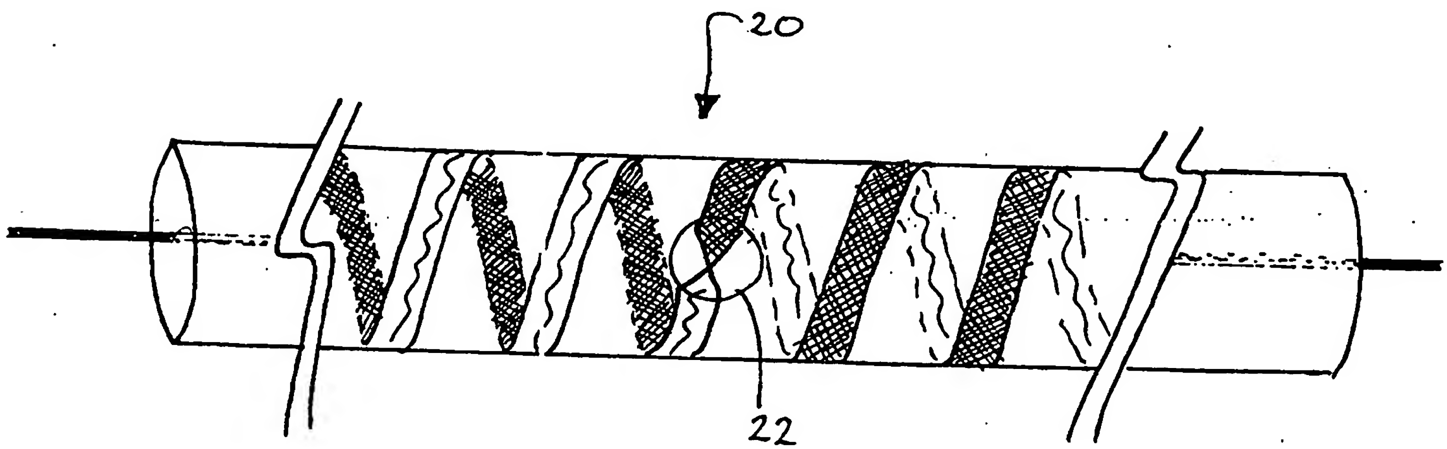

Fig. 10

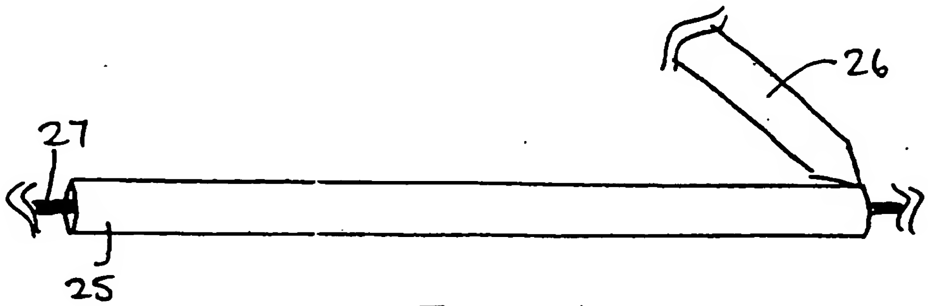

Fig 11a

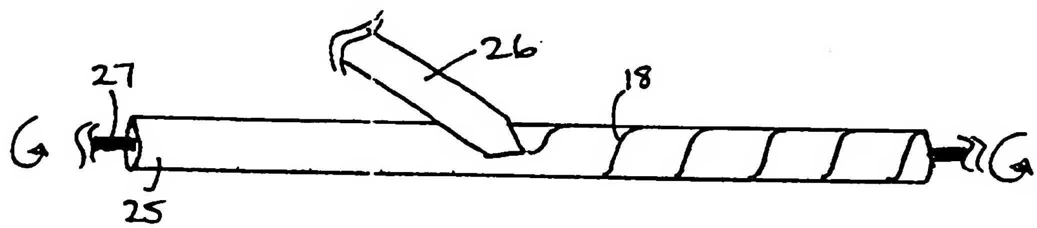

Fig 11b

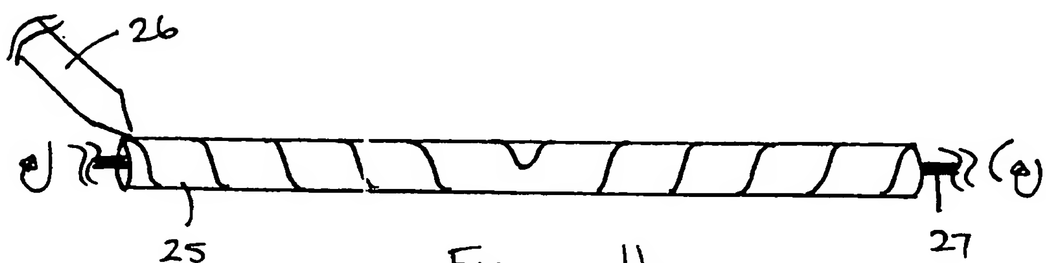

Fig 11c

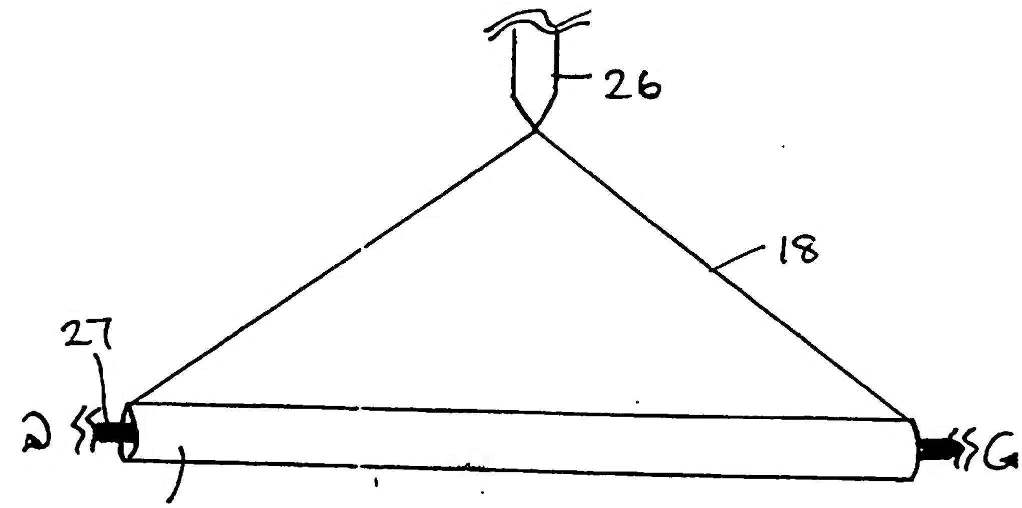

Fig 12a

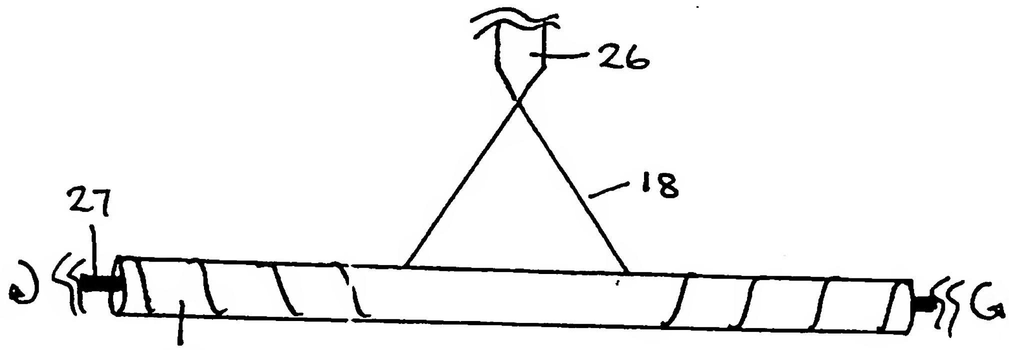

Fig 12b

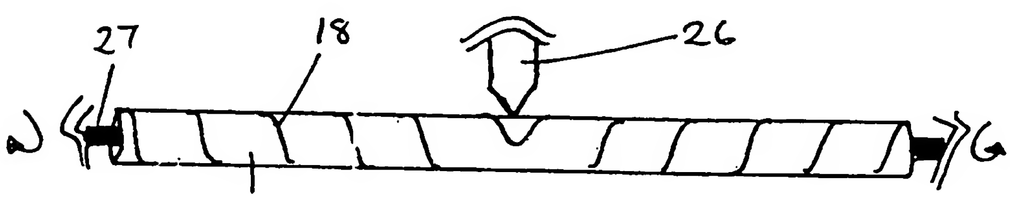

Fig 12c

Fig 13a

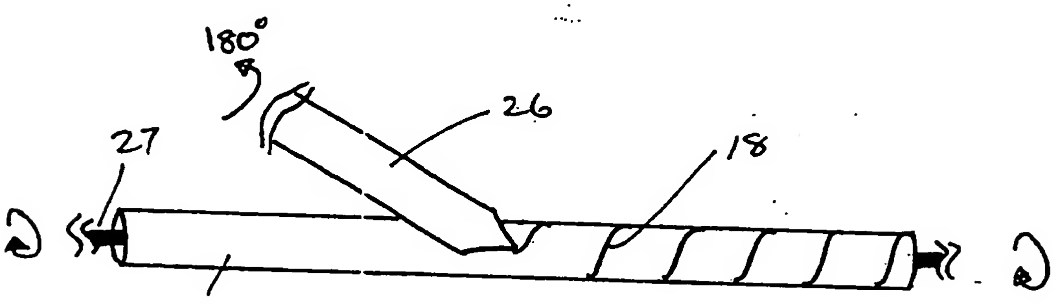

Fig 13b

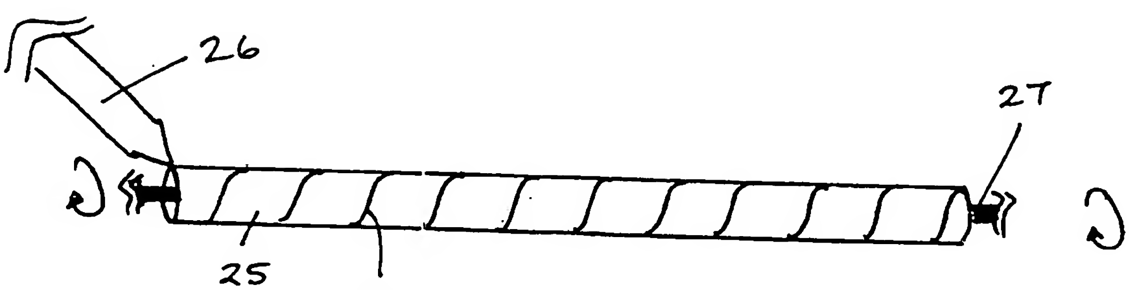

Fig 13c

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